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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,738	09/08/2003	Jotham W. Coe	PC25077A	8936

23913 7590 09/28/2006

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EXAMINER	
RAO, DEEPAK R	
ART UNIT	**PAPER NUMBER**
1624	

DATE MAILED: 09/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/657,738	COE ET AL.	
	Examiner	Art Unit	
	Deepak Rao	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 July 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) *9,11-13 and 17-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-30 and 32* is/are rejected.

7)☒ Claim(s) *1-8, 10, 14-16, 31* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to the amendment filed on July 26, 2006.

Claims 1-32 are pending in this application.

Election/Restrictions

This application contains claims 9, 11-13 and 17-24 drawn to an invention nonelected with traverse in Paper No. 20051114. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Withdrawn Rejections/Objections:

Applicant is notified that any outstanding rejection/objection that is not expressly maintained in this office action has been withdrawn or rendered moot in view of applicant's amendments and/or remarks.

The following rejections are maintained:

Claims 25-28 and new claims 29-30 and 32 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a pharmaceutical composition for treating anxiety, headache and migraine; or a method of treating anxiety, headache and migraine; does not reasonably provide enablement for a pharmaceutical composition for treating **all** disorders or conditions recited in claims 25-26; or a method of treating **all** disorders or conditions recited in claims 27-28; a method of treating a disease of the central nervous system

which is mediated by a nicotinic receptor (claim 29); a method of modulating cholinergic function in a patient (claim 30); and a method for binding neuronal nicotinic acetylcholine specific receptor sites in a patient (claim 32). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The reasons provided in the previous office action are incorporated here by reference.

Applicant's arguments have been fully considered but they were not deemed to be persuasive. Applicant argues that 'claims 25-28 are drawn to a limited list of disorders or conditions which are reasonably expected by those skilled in the art to benefit by treatment with compounds of the present invention'. The 'limited list of disorders' however, includes cognitive dysfunction, cognitive impairment, chemical dependencies, stroke, traumatic brain injury, etc. many of which are classified under neurodegenerative diseases or disorders of the central nervous system and are known to be very difficult to treat. See the reasons provided in the previous office action (provided below for convenience):

> Further, the instant claims includes a variety of conditions which fall within the meaning of "neurodegenerative diseases", see the claims reciting disorders such as disease-induced cognitive impairment arising from Alzheimer's disease, senile dementia, ... Parkinson's disease, multiple sclerosis, ALS, and much more. In fact, Layzer, Cecil Textbook of Medicine (article enclosed), states that "some degenerative diseases are difficult to classify because they involve multiple anatomic locations" (see page 2050). For example, Alzheimer's disease has traditionally been very difficult or impossible to prevent or even to treat effectively with chemotherapeutic agents. See e.g., the Cecil Textbook of Medicine, 20th edition (1996), Vol. 2, wherein it is stated that "[t]here is no cure for Alzheimer's disease, and no drug tried so far can alter the progress of the disease." (pg. 1994).

The list of disorders of the instant claims further includes 'chemical dependencies and addictions', the scope of which is beyond what has been established for such a treating effect. (The reasons provided in the previous office action are incorporated by reference and provided below for convenience):

> the notion that a compound could be effective against addiction in general is absolutely contrary to the current understanding of addiction generally. Although the term "addiction" implies a single entity, in fact it is a complex and variable network of services tailored to meet the multiple needs of the individual. There is not, and probably never will be, a pharmacological treatment for 'addiction' generally. That is because it is not a single disease or cluster of related disorders, but in fact, a collection with relatively little in common. Abuse of the use of barbiturates, alcohol, cocaine, opiates, amphetamines, benzodiazepines, nicotine, etc. all involve different parts of the CNS system; different receptors in the body. For example, cocaine binds at the dopamine reuptake transmitter. Abusive use of heroin, for example, arises from binding at the opiate receptors, cigarette addiction arises from some interaction at the nicotinic acid receptors, many tranquilizers involve the benzodiazepine receptor, alcohol involves yet another system, etc. All attempts to find a pharmaceutical to treat drug abuse generally have thus failed. Because addiction has so many dimensions and disrupts so many aspects of an individual's life, treatment for this illness is never simple.

The newly added claims 29-30 and 32 are drawn to 'a method of treating a disease of the central nervous system which is mediated by nicotinic receptor'; 'a method modulating cholinergic function in a patient'; and 'a method for binding neuronal nicotinic acetylcholine specific receptor sites in a patient' respectively. The specification pages 40-42 provide assays to measure the nicotinic receptor binding activity, however, there is no disclosure regarding how this data is applicable therapeutically in a method for binding neuronal nicotinic acetylcholine specific receptor sites in a patient generally; or a method of treating all types of diseases of the central nervous system mediated by nicotinic receptor modulating; or a method of modulating cholinergic function in a patient generally. The specification provides that the compounds are

useful in treating a variety of diseases of the central nervous system, see pages 20-21. As the instant claims are drawn to 'a method of modulating cholinergic function' and 'a method of binding neuronal nicotinic acetylcholine specific receptor sites in a patient', the claims are directed to 'a method of treating a diseases mediated by the activity recited in the claims' and the specification provides an exhaustive list of diseases that are associated with the recited activity, see pages 20-21.

The instant claims appear to be 'reach through' claims. 'Reach through' claims, in general have a format drawn to mechanistic, receptor binding or enzymatic functionality and thereby reach through any or all diseases, disorders or conditions, for which they lack written description and enabling disclosure in the specification thereby requiring undue experimentation for one of skill in the art to practice the invention. Further, the term "modulating" generally encompasses blocking, activating, partial blocking and partial activating. However, the compounds were not shown to have all these properties. For example, it is revolutionary for a compound to be effective as a blocker, activator and partial blocker/activator. The specification did not provide any competent tests or data to establish that the compounds have the claimed nicotinic receptor modulating activity' or 'cholinergic function modulating activity'. All the reasons provided in the previous office action for methods of treating various diseases, disorders or conditions apply to the instant claims 29-30 and 32.

The following rejections are necessitated by the amendment:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 29 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. Claim 29 recites the limitation "**composition** according to claim 1" in line 2. There is insufficient antecedent basis for this limitation in claim 1 on which claim 29 is dependent. Claim 1 is drawn to "a compound".
2. In claim 29, the recitation "a disease of the central nervous system which is mediated by a nicotinic receptor modulating composition of claim 1" is confusing. It is not clear if applicant intends treatment of a disease mediated by "nicotinic receptor modulating composition according claim 1", thereby it appears as though the disease is caused by the composition comprising the compound of claim 1. It is not clear if the composition comprising the compound of claim 1 is a therapeutic agent to treat the disease or it is the one that causes the disease.
3. Claim 30 recites the limitation "**composition** according to claim 1" in line 2. There is insufficient antecedent basis for this limitation in claim 1 on which claim 29 is dependent. Claim 1 is drawn to "a compound".

Duplicate Claims

Applicant is advised that should claim 31 be found allowable, claims 25 and 27 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing,

despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claims 25 and 27 recite the same composition as claim 31 with the exception of an intended use which is not given any patentable weight.

Allowable Subject Matter

Claims 1 along with dependent claims 2-8, 14-16 and 31 are objected to for containing nonelected subject matter (in claim 1), but will be allowable if rewritten eliminating the nonelected subject matter.

***Note**: If claim 1 is amended to include the limitation of the elected subject matter (i.e., **m =1 and n = 2**), then claim 10 will be a substantial duplicate and deletion of claim 10 is suggested.*

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

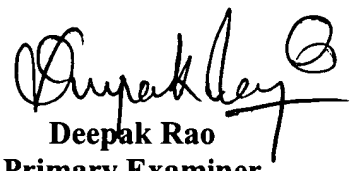
CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (571) 272-0672. The examiner can normally be reached on Tuesday-Friday from 6:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Deepak Rao
Primary Examiner
Art Unit 1624

September 24, 2006